

REMARKS

Status of Claims:

In the specification, paragraphs [0051], [0054], and [0055] are amended.

Claims 1, 3, 10, 15, 24, 29, and 31 are amended. New claims 34-40 are added. Thus, claims 1-40 are presented for examination.

Claim and Specification Objections:

The Examiner states that claims 24-28 “evoked sixth paragraph, means-plus-function language”, and thus objects to claims 24-28 for lacking support in the specification for the means-plus-function elements.

With respect to claims 24-28, the objections are respectfully traversed.

Claims 26, 27, and 28 do not recite “means-plus-function” language and are dependent upon other claims (claims 1, 10, and 15) that do not recite “means-plus-function” language.

For claims 24 and 25, paragraphs [0051], [0054], and [0055] have been amended to provide specific examples of “means for positioning a base on an infusion site of a user”, “means for positioning a connector onto the base”, and “means for adjusting a position of the delivery tubing”. Thus, it is submitted that claims 24-25 fully satisfy the disclosure requirements under 35 U.S.C. §112.

Claim Rejections over Fischell:

Claims 1-30 are rejected under 35 U.S.C. §102(b) as being anticipated by Fischell (U.S. Patent No. 5,545,143).

With respect to claims 1-30, the rejections are respectfully traversed.

For claim 1, the Examiner acknowledges that the device in Fischell is not designed to be rotated, but states that “[i]f the connector is rotated about an axis that is perpendicular to said first surface with enough force the stops can conceivably break and the connector would be rotatable to any degree between 0 and 360.” (See page 4 of the Office Action). The examiner used similar reasoning to reject claims 29-30.

Per MPEP §2131, to anticipate a claim, the reference must teach every element of the claim. The Examiner’s use of a prior art device in a broken state as evidence of anticipation for an disclosed element is inconsistent with the requirements of anticipation, and is unsupported by case law. In *Clough v. Gilbert & Baker mfg.*, 106 U.S. 166 (1882), the Supreme Court held that the prior device capable of being adjusted to operate in the same manner as the patented device did not anticipate. In *Topliff v. Topliff*, 145 U.S. 156 (1892), the Supreme Court held that a prior device capable of slight modification so as to operate in the same manner as the patented device did not anticipate. In suggesting the breaking of the stops in the Fischell device with sufficient force, the Examiner is suggesting an adjustment and a modification to the prior art device, which is not a sufficient ground for anticipation.

In addition, the Fischell device is a medical device used for subcutaneous injection. Its intended users are medical professionals and patients. The inherent nature of such device teaches away for the use suggested by the Examiner. It is known to those skilled in the art that users of medical devices generally do not purposely break the medical device, and generally do not use medical devices in a broken state. Hence, the use suggested by the examiner requiring the breaking of one element by force is not an “inherent use” of the Fischell device.

Furthermore, if the Fischell device is used in the manner suggested by the Examiner, the device does not teach every element of the claimed invention. Fischell states that, “when the connector 241 is positioned just above the main body 210 as shown in FIG. 15, a downward finger pressure can be used to push the locking pins 246 into the tapered entry holes 226”, and that, “[w]hen this is accomplished, the lip 225 of the cannula section 220 is locked onto the mating lip 247 of the locking pins 246.” (Fischell; FIG. 16; column 12, lines 39-45). It is clear

from Fischell that the purpose of the locking pins 246 is to secure the connector 241 onto the cannula section 220. Fischell states that when the locking pins 246 disengages the lips 225 of the cannula section 220, the connector 241 becomes detached from the cannula section 220.

(Fischell; column 12, lines 48-50.) Hence, if the Fischell device is used in the manner suggested by the Examiner, by using force to break the stops (locking pins 246), the connector 241 becomes detached from the cannula section 220. Claim 1 of the present invention recites that “wherein the connector is rotatable on the base ... when the connector is removably attached to the base.” The connector in the Fischell device cannot be adapted to become rotatable while still attached to the base, because the locking pins 246 serves the function of attaching the connector to the base.

As amended, claim 1 now recites “wherein the connector comprises at least one stop for inhibiting rotation of the connector beyond 360 degrees.” This limitation further distinguishes applicant’s invention over the Fischell device. As discussed above, the connector (241) of the Fischell device is not designed to be rotatable. If the stops (locking pins 246) of Fischell is broken by force, as the Examiner suggests, then the connector does not comprise a stop capable of inhibiting rotation of the connector beyond 360 degrees. Thus, it is submitted that Fischell, if used in the state suggested by the examiner, does not teach every element of the invention.

In light of the reasons stated, it is submitted that the Examiner has not made out a case of anticipation under 35 U.S.C. §102(b) based on the Fischell reference for independent claims 1, 10, 15, 24, and 29. Claims 2-9, 11-14, 16-23, 25-28, and 30 are dependent claims of claims 1, 10, 15, 24, or 29, and thus are patentable over Fischell as well.

Claim Rejections over Douglas:

Claims 1-3, 5-17, 19-29 are rejected under 35 U.S.C. §102(e) as being anticipated by Douglas et al. (U.S. Patent No. 6,685,674).

With respect to claims 1-3, 5-17, and 19-29, as amended, the rejections are respectfully traversed.

Independent claims 1, 10, 15, 24, and 29 are amended to recite the limitation of the connector comprising “at least one stop for inhibiting rotation of the connector beyond 360 degrees”. This element is neither described nor suggested by Douglas.

On page 5 of the Office Action, the Examiner points to element 17 of Douglas as a stop. Douglas describes element 17 as a lip on the housing 40 which matches the interior grooves 41 of the base, such that the housing 40 can be attached to the base. (Douglas, column 5, lines 1-10). While the lip 17 inhibits the connector from detaching from the base, it does not inhibit the rotational movement of the connector. Douglas clearly states that the “housing 40 may freely be rotated in direction R.” (Douglas, column 5, lines 9-10.) Douglas does not teach or suggest a stop on the connector inhibiting rotation of the connector beyond 360 degrees with respect to the base.

To anticipate a claim, the reference must teach every element of the claim. For the reasons stated above, it is thus submitted that independent claims 1, 10, 15, 24, and 29 are allowable over Douglas. Dependent claims 2-3, 5-9, 11-14, 16-17, 19-23, and 25-28 are dependent claims of claims 1, 10, 15, 24, or 29, and thus are allowable as well for at least the same reasons.

Allowable Subject Matter:

Applicant expresses appreciation to the Examiner for the indication that claims 31-33 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 31 has been amended to include all limitations of the base claim (claim 29) and all intervening claims (claim 30). Hence, claim 31 is believed to be allowable. Claims 32-33 are dependent claims of the allowable claim 31, and therefore are allowable as well.

Since claim 29 has been amended and is believed to be allowable over the prior arts, new claims 34-36 are added to capture the same scope previously captured by claims 31-33.

Conclusion:

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

Respectfully submitted,

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